

1 **IN THE UNITED STATES DISTRICT COURT**
2 **FOR THE DISTRICT OF SOUTH CAROLINA**
3 **CHARLESTON DIVISION**

4
5
6 **Louis C. Sanfilippo, M.D., an**
7 individual,

8 Plaintiff,

9 v.

10 **Timothy David Brewerton, M.D., an**
11 individual,

12 Defendant.

Case No. 2:17-CV-183-RMG-BM

LOUIS C. SANFILIPPO, M.D.'S
PRO SE COMPLAINT

(DEMAND FOR JURY TRIAL)

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15 The Plaintiff, Louis C. Sanfilippo, M.D. ("Plaintiff"), herein files this Complaint
16 against Defendant Timothy David Brewerton, M.D. ("Brewerton"), and would allege
17 and show as follows:

18 **JURISDICTION AND VENUE**

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20 1. This Court has subject matter jurisdiction over the claims herein under 28
21 U.S.C. § 1332(a)(1), which provides for "original jurisdiction of all civil actions where
22 the matter in controversy exceeds the sum or value of \$75,000 . . . and is between . . .
23 citizens of different States." Here, the amount in controversy is at least \$300,000,000
24 (\$300 Million) as explained further herein.

25 2. This Court has personal jurisdiction because Defendant Brewerton resides
26 in South Carolina, and has incurred the liability complained of herein in South Carolina.

27 3. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b).
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PARTIES

4. Plaintiff resides in and is a citizen of the State of New Jersey.

5. Upon information and belief, Defendant Brewerton resides in and is a citizen of the State of South Carolina.

GENERAL ALLEGATIONS

6. U.S. Patent 8,318,813 (see Exhibit 1 attached hereto), which claims an invention priority date of September 13, 2007 and was issued by the United States Patent and Trademark Office on November 27, 2012, claims methods for the treatment of Binge Eating Disorder as defined in the DSM-IV-TR with the drug lisdexamfetamine dimesylate (*i.e.*, Vyvanse®). The patent's lone inventor is the Plaintiff.

7. On May 9, 2014, a Petition for an *Inter Partes Review* for U.S. Patent 8,318,813 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123 (see Exhibit 2 attached hereto), made by Shire Development LLC, was provided to the patent's then-owner LCS Group, LLC by serving the law firm Cantor Colburn LLP (see page 71, last page, of Exhibit 2).

8. Shire's *Inter Partes Review* Petition relied completely and exclusively on a Declaration by Defendant Brewerton, which he signed on May 8, 2014 (see Exhibit 3 attached hereto; signature line on page 101).

9. Four highly substantiated, evidence-based documents (see Exhibits 4, 5, 6 and 7 attached hereto) contextualize and representationally profile Defendant Brewerton's Declaration, and thereby the Petition which exclusively relied on it, in view of the medical literature on eating disorders, obesity and stimulant drugs, including profiling Defendant Brewerton's Declaration representations against his own published work related to the diagnosis and treatment of eating disorders. Each of these four evidence-based documents discloses and explains the Defendant's extensive use of misleading statements and egregious misrepresentations of the medical literature (including for their "line of reasoning"), as well as characterizes and explains the

1 Defendant's extensive omission of materially relevant and important information
2 (including from his own publications), in concluding that all the claims of U.S. Patent
3 No. 8,318,813 would have been "obvious" to a Person of Ordinary Skill in the Art as of
4 September 13, 2007 and therefore should all be invalid. One particularly focused
5 contextualization and profile of the Defendant Brewerton and his Declaration can be
6 found on pages 46-171 of Exhibit 4 in the section titled "EXAMPLE 7: 'Profiling the
7 Declarant and his Declaration.'"

8 10. Two published medical articles immediately preceding U.S. Patent No.
9 8,318,813's priority date of September 13, 2007 (see Exhibits 8 and 9 attached hereto,
10 respectively, Surman et. al. published March 2006 and Biederman et. al. published in
11 August 2007) demonstrate that Defendant Brewerton egregiously misrepresented key
12 case studies (for their proper medical context and implications) on which the Patent
13 Trial & Appeal Board relied to institute, and to proceed with, a trial regarding the patent
14 (see pages 19-26 of Patent Board's Decision, in particular pages 20-21, of Exhibit 10
15 attached hereto). The specific nature by which Defendant misrepresented the proper
16 medical context of these studies and their implications, in direct contradiction to their
17 actual significance, context and implications, is extensively characterized in Exhibit 4
18 (see pages 13-20, 84-89, 102-105, 164-165), as well as in Exhibit 6 (see pages 10-16)
19 and Exhibit 7 (see pages 17-18 or 12-13 of the "Supplemental Information," Point No.
20 2; see pages 22-23 or 17-18 of the "Supplemental Information," Point No. 2; see pages
21 32-35 or 27-30 of the "Supplemental Information"; see page 46 or 41 of the
22 "Supplemental Information"; see pages 49-50 or 44-45 of the "Supplemental
23 Information"). As characterized in those Exhibits and further below in paragraph 17,
24 Defendant Brewerton appears to have "plagiarized" these cases from Surman's 2006
25 study, except that he misrepresented their proper context, significance and implications
26 to the Patent Board, and omitted materially important and relevant information from his
27 own published work that would have cast proper light on them.

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FIRST CLAIM FOR RELIEF—FRAUD

11. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates them herein by reference.

12. Defendant made numerous false representations regarding relevant and important teachings in the medical literature related to the validity of the Plaintiff's invention, including at least the following: (a) that a Person of Ordinary Skill in the Art ("POSA," as defined in Defendant's Declaration, see Exhibit 3, page 19, Paragraphs 27 and 28) "as of September 2007" would have regarded it acceptable to treat Bulimia Nervosa (or its symptom of binge eating thereof) with a psychostimulant drug (as used to treat Attention Deficit Hyperactivity Disorder), such as lisdexamfetamine dimesylate, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in the Exhibits and their referenced pages aforementioned in paragraph 10 above, including Exhibits 8 and 9; (b) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded stimulant drugs (as used to treat Attention Deficit Hyperactivity Disorder), such as lisdexamfetamine dimesylate, to have a reasonable expectation of success (including safety) in treating Bulimia Nervosa, such that it would have been obvious to use a stimulant drug such as lisdexamfetamine dimesylate for the treatment of Bulimia Nervosa with a reasonable expectation of success, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in the Exhibits and their referenced pages aforementioned in paragraph 10 above, including Exhibits 8 and 9; (c) that a Person of Ordinary Skill in the Art "as of September 2007" would have regarded it acceptable to treat Obesity with a psychostimulant drug (as used to treat Attention Deficit Hyperactivity Disorder), especially lisdexamfetamine dimesylate, as explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see pages 10-13), Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page 6 or page 1 of the "Supplemental Information"; see page 17 or page 12 of the "Supplemental

1 Information,” Point No. 1; see pages 21-22 or pages 16-17 of the “Supplemental
2 Information,” Point No. 1); (d) that a Person of Ordinary Skill in the Art “as of
3 September 2007” would have regarded stimulant drugs (as used to treat Attention
4 Deficit Hyperactivity Disorder), especially lisdexamfetamine dimesylate, to have a
5 reasonable expectation of success (including safety) in treating Obesity, such that it
6 would have been obvious to use a stimulant drug (especially lisdexamfetamine
7 dimesylate) for the treatment of Obesity with a reasonable expectation of success, as
8 explained for its falsity in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see
9 pages 10-13), Exhibit 5 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page
10 6 or page 1 of the “Supplemental Information”; see page 17 or page 12 of the
11 “Supplemental Information,” Point No. 1; see pages 21-22 or pages 16-17 of the
12 “Supplemental Information,” Point No. 1); (e) that a Person of Ordinary Skill in the Art
13 “as of September 2007” would have regarded lisdexamfetamine dimesylate as an
14 acceptable “anti-obesity agent,” as to regard the use of lisdexamfetamine dimesylate for
15 the treatment of Obesity as an acceptable medical treatment, as explained for its falsity
16 in Exhibits 4, 5, 6 and 7 though particularly in Exhibit 4 (see pages 10-13), Exhibit 5
17 (see pages 1-20), Exhibit 6 (see pages 1-10), Exhibit 7 (see page 6 or page 1 of the
18 “Supplemental Information”; see page 17 or page 12 of the “Supplemental
19 Information,” Point No. 1; see pages 21-22 or pages 16-17 of the “Supplemental
20 Information,” Point No. 1); (f) that the invention which claims methods to treat Binge
21 Eating Disorder as defined in the DSM IV-TR with the drug lisdexamfetamine
22 dimesylate would have been obvious to a Person of Ordinary Skill in the Art “as of
23 September 2007,” as characterized for its falsity in Exhibits 4, 5, 6 and 7, though
24 particularly on pages 17-27 of Exhibit 6; and (g) that the invention which claims
25 methods to treat Binge Eating Disorder as defined in the DSM IV-TR with the drug
26 lisdexamfetamine dimesylate would have been regarded to have a reasonable
27 expectation of success (including safety) to a Person of Ordinary Skill in the Art “as of
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1 September 2007,” such that it would have been obvious to use a stimulant drug (such as
2 lisdexamfetamine dimesylate) for the treatment of Binge Eating Disorder as defined in
3 the DSM-IV-TR with a reasonable expectation of success, as characterized for its falsity
4 in Exhibits 4, 5, 6 and 7, though particularly on pages 17-27 of Exhibit 6.

5 13. Defendant made numerous false representations regarding the “line of
6 reasoning” of a POSA as of September 13, 2007 in his three core arguments to allege
7 the obviousness of the patent’s three independent claims (claim Nos. 1,8 and 13; see p.
8 15 of Exhibit 1 attached hereto). These three core arguments are referred to, in both the
9 Petition and Declaration, as the Grounds 1, 4 and 7 arguments (for Petition, see Exhibit
10 2 - Ground 1 on pages 23-28, Ground 4 on pages 36-42, Ground 7 on pages 49-54; for
11 Declaration see Exhibit 3 - Ground 1 on pages 39-42, Ground 4 on pages 49-55, Ground
12 7 on pages 62-67). The nature and extent of these false representations are more
13 specifically characterized below (*i.e.*, paragraphs 14, 15, 16 and 17). Importantly, the
14 Patent Board dismissed Defendant’s Ground 1 line of reasoning but accepted his
15 Ground 4 and Ground 7 line of reasoning to support its decision to institute the *Inter*
16 *Partes Review* trial that led to the invalidation of all the patent’s claims.

17 14. More specifically with respect to the allegations made in Paragraph 13,
18 Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of
19 September 13, 2007 for the “Ground 1 line of reasoning,” in particular how a POSA
20 would have relied on Mickle’s U.S. Patent Application No. 2007/0042955 “Abuse
21 Resistant Amphetamine Prodrugs,” most notably on one sentence within its disclosures,
22 to reason that lisdexamfetamine dimesylate was an acceptable and reasonably successful
23 “anti-obesity agent” for clinical use in the pharmacologic treatment of obesity, as to
24 therefore have been regarded by a POSA as of September 13, 2007 to be an acceptable
25 and reasonably successful drug in the treatment of Binge Eating Disorder as defined in
26 the DSM-IV-TR which is a disorder associated (though not clinically defined) with
27 clinical obesity, as represented in his Declaration by the following line of reasoning,
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1 “Because of the success of these [d-fenfluramine and sibutramine] centrally acting anti-
2 obesity agents in the treatment of BED [per Appolinario], a POSA would have had a
3 reasonable expectation of success that other centrally acting anti-obesity agents would
4 similarly reduce binge eating behavior” (Exhibit 3, p. 40-41)..... “As a result, a POSA
5 would have been motivated to identify another centrally acting anti-obesity agent with
6 positive properties, such as LDX-dimesylate as described by Mickle.” (Exhibit 3, p.
7 41).... “Mickle teaches amphetamine prodrugs, such as LDX-dimesylate, that are
8 indicated for the treatment of certain disorders, including obesity... In fact, obesity is
9 identified as a preferred indication.....” (Exhibit 3, p. 41-42).... “In light of the
10 teachings of Appolinario together with Mickle, a POSA would have diagnosed BED
11 according to the DSM-IV-TR and would have had a reasonable expectation of success
12 in treating BED with LDX-dimesylate.” (Exhibit 3., p. 42).... “Thus, it is my opinion
13 that... claim 1 would have been obvious over the combination of Appolinario and
14 Mickle....claim 8 would have been obvious over the combination of Appolinario and
15 Mickle for the same reasons that Claim 1 would have been obvious....claim 13 would
16 have been obvious over the combination of Appolinario and Mickle for the same
17 reasons that claim 1 would have been obvious over the combination of Appolinario and
18 Mickle.” (Exhibit 3, pages 42, 45, 47). An explanation for the extent and egregiousness
19 of this misrepresented “Ground 1 POSA line of reasoning” can be found on pages 10-13
20 of Exhibit 4, but is also characterized in Exhibit 5 (see pages 1-20), Exhibit 6 (see pages
21 1-10), and Exhibit 7 (see page 6 or page 1 of the “Supplemental Information”; see page
22 17 or page 12 of the “Supplemental Information,” Point No. 1; see pages 21-22 or pages
23 16-17 of the “Supplemental Information,” Point No. 1).

24 15. More specifically with respect to the allegations made in Paragraph 13,
25 Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of
26 September 13, 2007 for the “Ground 4 line of reasoning,” in particular how a POSA as
27 of September 13, 2007 would have relied on a study from 1983 (Ong), which involved a
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1 **one-time dose of intravenous (IV) methylamphetamine** to experimentally treat
2 patients with Bulimia Nervosa, to reason to the “obviousness” and “reasonable
3 expectation of success” of lisdexamfetamine dimesylate to treat Binge Eating Disorder
4 as defined in the DSM-IV-TR, as represented in his Declaration by the following line of
5 reasoning, “A POSA would have known that the symptom of bulimia as studied in Ong
6 closely resembles the symptom of binge eating described in the DSM-IV-TR for both
7 BN and BED” (Exhibit 4, p. 50) “Therefore, a POSA reading Ong and the DSM-IV-
8 TR would have learned to treat BED by diagnosing the patient and administering [a one-
9 time dose of intravenous] methylamphetamine to the patient. And based upon the
10 teachings of Ong and the DSM-IV-TR, a POSA would have had a reasonable
11 expectation of success of treating BED with [a one-time dose of intravenous]
12 methylamphetamine used in Ong.” (Exhibit 4, p. 52)... “Yet, a POSA would have also
13 recognized from Ong that ‘drugs with stimulant and euphoric effects carry the dangers
14 of drug dependence and drug induced psychosis...’ Such a warning would have led and
15 motivated the POSA to seek an alternative stimulant that could provide similar
16 properties as [a one-time dose of intravenous] methylamphetamine given its success as a
17 treatment in Ong.” (Exhibit 4, p. 52).... “A POSA would have been motivated to replace
18 [the one-time dose of intravenous] methylamphetamine as disclosed in Ong with [oral]
19 LDX dimesylate of Mickle. As noted above, Ong cautions about the dangers of
20 dependence and drug-induced psychosis for drugs with stimulant and euphoric effects,
21 with LDX dimesylate designed to exhibit reduced euphoric effects associated with
22 abuse. Further, a POSA would have expected that LDX dimesylate would have the
23 same pharmacological effects as [a one-time dose of intravenous]
24 methylamphetamine....” (Exhibit 3, p. 54).... “Therefore, based on the disclosures of
25 Mickle, a POSA would have had a reasonable expectation of successfully treating BED
26 by replacing [a one-time dose of intravenous] methylamphetamine with LDX
27 dimesylate....” (Exhibit 3, p. 55).... “In light of the teachings of Ong together with
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1 DSM-IV-TR and Mickle, a POSA would have diagnosed BED according to the DSM-
2 IV-TR and would have had a reasonable expectation of success of treating BED with
3 LDX dimesylate.”(Exhibit 3, p. 55). . . . “Thus, . . . it is my opinion that . . . claim 1 would
4 have been obvious over the combination of Ong together with DSM-IV-TR and Mickle
5 claim 8 would have been obvious over the combination of Ong, DSM-IV-TR, and
6 Mickle for the same reasons that Claim 1 would have been obvious . . . claim 13 would
7 have been obvious over the combination of Ong, DSM-IV-TR, and Mickle for the same
8 reasons that claim 1 would have been obvious . . . ” (Exhibit 3, pages 55, 58, 60). An
9 explanation for the extent and egregiousness of this misrepresented “POSA Ground 4
10 line of reasoning” can be found, in particular, on pages 42-46 of Exhibit 4 in the section
11 titled “EXAMPLE 6. ‘Clinical data from a one-time IV injection of an amphetamine-
12 based drug in Bulimia Nervosa patients would lead an MD/psychiatrist to conclude
13 LDX dimesylate’s ‘reasonable expectation of success’ for the treatment of BED
14 patients.”

15 16. More specifically with respect to the allegations made in Paragraph 13,
16 Defendant Brewerton egregiously misrepresented the line of reasoning of a POSA as of
17 September 13, 2007 for the “Ground 7 line of reasoning,” in particular how a POSA as
18 of September 13, 2007 would have relied on an experimental study involving co-morbid
19 ADHD and Bulimia Nervosa patients from 2005 (Dukarm) involving the use of d-
20 amphetamine, to reason to the “obviousness” and “reasonable expectation of success” of
21 lisdexamfetamine dimesylate to treat Binge Eating Disorder as defined in the DSM-IV-
22 TR, as represented in his Declaration by the following line of reasoning, "As previously
23 discussed, an essential feature of both BN and BED in DSM-IV-TR is ‘recurrent
24 episodes of binge eating’ According to the DSM-IV-TR a ‘recurrent episode of binge
25 eating’ in BED is the same as a ‘recurrent episode of binge eating in BN.’ (Exhibit 3, p.
26 63). . . . “Thus, it would have been clear to a POSA that the characteristics of the binge
27 eating episodes in BED are essentially the same as those in BN.” (Exhibit 3, p.

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64)..... “Based on the teachings of the DSM-IV-TR, it is my opinion that the binge eating of BN is the same as the binge eating of BED.” (Exhibit 3, p. 65)..... “.....given the evidence of Dukarm demonstrating that d-amphetamine was successful in eliminating the binge eating in patients with BN, a POSA would have had a reasonable expectation of success in treating with BED with d-amphetamine.” (Exhibit 3, p. 65)..... “A POSA would have been motivated to replace d-amphetamine as disclosed in Dukarm [to treat co-morbid ADHD and Bulimia Nervosa patients] with LDX dimesylate for the treatment of BED” (Exhibit 3, p. 66) “In light of the teachings of Dukarm together with the DSM-IV-TR and Mickle, a POSA would have diagnosed BED according to the DSM-IV-TR and would have had a reasonable expectation of success of treating BED with LDX dimesylate.” (Exhibit 3, p. 66-67)..... “Thus, ... it is my opinion that....claim 1 would have been obvious over the combination of Dukarm together with DSM-IV-TR and Mickle.claim 8 would have been obvious over the combination of Dukarm, DSM-IV-TR, and Mickle for the same reasons that Claim 1 would have been obvious.....claim 13 would have been obvious over the combination of Dukarm, DSM-IV-TR, and Mickle for the same reasons that claim 1 would have been obvious....” (Exhibit 3, pages 62, 69-70, 71). An explanation for the extent and egregiousness of this misrepresented “POSA Ground 7 line of reasoning” can be found in Paragraph 10 above.

17. The extent and egregiousness of Defendant’s misrepresented “POSA Ground 7 line of reasoning” is also succinctly characterized for its misleading and misrepresented nature in view of Surman’s 2006 publication that unambiguously characterizes the state of the art of treating Bulimia Nervosa in 2006 as follows (bold emphasis added), “Considering that **ADHD and Bulimia Nervosa respond to different pharmacologic treatments**, diagnosing ADHD in subjects with bulimia nervosa could lead to new therapeutic opportunities to this debilitating and life-threatening disorder” (p. 2, Exhibit 8) and “Since **bulimia nervosa and ADHD require different pharmacologic**

1 **approaches**, clinical evaluations of women with bulimia nervosa may benefit from
2 systematic identification of ADHD and vice versa” (p. 3, Exhibit 8). In other words,
3 stimulant drugs (as a well-known mainstay treatment for ADHD) clearly would not have
4 been regarded by the psychiatric community (*i.e.*, POSA’s, as defined above) to be an
5 acceptable, and thus reasonably successful, pharmacologic treatment of Bulimia
6 Nervosa at the time of the invention’s priority date in September 2007. Rather, their use
7 to treat Bulimia Nervosa would have been discouraged, except perhaps in such instances
8 where the stimulant was being used in patients with co-morbid ADHD and Bulimia
9 Nervosa. So when the Defendant represents that (bold emphasis added) “it is my
10 opinion that given the overlapping symptom of binge eating in BN and BED described
11 in the DSM-IV-TR, together with **extensive data** demonstrating the successful use of
12 psychostimulants in the treatment of binge eating described in Dukarm [which featured
13 co-morbid Bulimia Nervosa and ADHD patients], a POSA would have had a reasonable
14 expectation of success in extending the teachings of Dukarm to the treatment of BED
15 [with a stimulant]” (p. 84, Exhibit 3), he is egregiously misrepresenting and
16 misconstrualizing the most critical point of Dukarm’s -- and also Surman’s -- studies
17 that relate to patients with **co-morbid** Bulimia Nervosa and ADHD or ADHD-like
18 symptoms in which the rationale for using a stimulant is foremost to treat the ADHD
19 symptoms (and without ADHD symptoms, a stimulant to treat Bulimia Nervosa would
20 have been ill-advised and discouraged at the time of the invention). The fraudulent
21 nature of the Defendant’s “Ground 7 line of reasoning” is made evident in view of how
22 the same exact cases that the Defendant represents as “**extensive data**” involving the
23 use of stimulants to treat Bulimia Nervosa are represented by Surman, in the peer-
24 reviewed Journal of Clinical Psychiatry, as “**scant reports** in the medial literature of
25 adults suffering from both ADHD-like symptoms and bulimia nervosa” (p. 2, Exhibit
26 8). Moreover, the significance of these cases is that they show a putative link between
27 ADHD and Bulimia Nervosa which, in fact, Surman found in his study with
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1 “significantly greater rates of bulimia nervosa were identified in women with versus
2 without ADHD (12% vs. 3%)” (p. 1, Exhibit 8, see “Results”). In this respect,
3 Defendant was motivated to use misrepresented context to deceive the Patent Board into
4 perceiving the medical literature one way (*i.e.*, that stimulants were well-regarded as
5 acceptable and reasonably successful treatments of Bulimia Nervosa based on
6 “extensive data”) when its true reality in the medical literature was the diametric
7 opposite (*i.e.*, that there were “scant case reports in the medial literature of adults
8 suffering from both ADHD-like symptoms and bulimia nervosa” which showed that
9 stimulants seemed to help not only ADHD symptoms but also Bulimia Nervosa
10 symptoms such as binge eating in these scant reports thus suggesting a possible
11 association/risk between these two disorders). Thus, it would appear that the Defendant
12 plagiarized these case “scant case reports” to allege the obviousness of the patent’s
13 claims, except that the act of plagiarism did not involve actually copying them in their
14 proper medical context but, rather, profoundly misrepresenting their context, as if these
15 “scant reports” were long-recognized and well-regarded in the psychiatric community
16 and among POSA’s “as extensive data” to support treatment of Bulimia Nervosa with
17 stimulant drugs (as used to treat ADHD). It is not surprising, therefore, that the
18 Defendant did not cite or include Surman’s publication in his Declaration, as it would
19 have completely undermined and refuted his Declaration testimony, as well as
20 “sourced” his deceptive testimony.

21 18. The Defendant repeatedly and egregiously contradicted relevant and important
22 material regarding the treatment of eating disorders from his own published work, but
23 failed to disclose that published work to the Patent Board, as profiled and explained on
24 pages 20-26 of Exhibit 4 in the section titled “Example 3: Self-Contradictory
25 Representations in view of the Declarant’s own Prior Representations.” The Defendant
26 also negligently failed to disclose materially relevant and important teachings from his
27 own prior work related to the patent’s claims, which involve a “therapeutically effective
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1 amount” of lisdexamfetamine dimesylate to treat Binge Eating Disorder as defined in
2 the DSM-IV-TR. For instance, one of the most relevant and important published works
3 in the art of eating disorders that could have helped the Patent Board understand how a
4 POSA as of September 13, 2007 would have regarded the pharmacological treatment of
5 “Binge Eating Disorder as defined in the DSM-IV-TR” (as featured in the patent’s
6 claims) would have been an article Defendant Brewerton published in 2004 in
7 “Psychiatry Times” titled “Pharmacotherapy for Patients with Eating Disorders” (see
8 Exhibit 11 attached hereto). The publication identifies acceptable and reasonably
9 successful pharmacologic treatments for Anorexia Nervosa, Bulimia Nervosa and Binge
10 Eating Disorder. The latter section, on BED, would have been directly and materially
11 relevant to how a POSA in September 2007 would have regarded acceptable and
12 reasonable successful pharmacologic treatments of Binge Eating Disorder as defined in
13 the DSM-IV-TR (as featured in the patent’s claims). For example, of the numerous
14 studies identified for the appropriate pharmacologic treatment of Binge Eating Disorder
15 (according to DSM-IV/IV-TR criteria) in Defendant Brewerton’s 2004 publication,
16 which Defendant concealed from the Patent Board, not a single one of them involved a
17 stimulant (as used to treat ADHD). Nor was a stimulant referenced in any of the studies
18 cited in Defendant Brewerton’s 2004 publication to provide evidence that stimulants (as
19 used to treat ADHD) might be an acceptable and reasonably successful treatment class
20 of drugs for Bulimia Nervosa, further supporting the allegation for fraud.

21 19. Further, the Defendant failed to cite or include a textbook he exclusively
22 edited, titled “Clinical Handbook of Eating Disorders” published in 2004, that
23 extensively addressed acceptable and successful pharmacotherapies for eating disorders,
24 including Bulimia Nervosa and Binge Eating Disorder (see Exhibit 12 attached hereto
25 for book’s table of contents and Chapters 11 and 21). More specifically, Chapter 21 of
26 the Defendant’s exclusively edited book, titled “Psychopharmacology of Anorexia
27 Nervosa, Bulimia Nervosa and Binge Eating Disorder” and which nicely captures the
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1 eating disorder “state of the art” shortly before the invention’s priority date, nowhere
2 identifies stimulants (as used to treat ADHD) as acceptable or successful
3 pharmacotherapy for any eating disorder (see pp. 30-49 of Exhibit 12). Defendant
4 willfully omitted disclosure of these highly relevant and important 2004 references to
5 the Patent Board because it would have completely belied his testimony alleging the
6 obviousness of the ‘813 Patent’s claims to treat Binge Eating Disorder as defined in the
7 DSM-IV-TR with the stimulant drug lisdexamfetamine dimesylate. Rather, had
8 Defendant disclosed his 2004 publications and their implications to the Patent Board, it
9 would have supported the non-obviousness and validity of the patent, as well as exposed
10 a pervasive pattern of extremely negligent, deceptive and miscon contextualized
11 representations involving the medical literature in his Declaration.

12 20. The Defendant’s 2004 publication “Pharmacotherapy for Patients with
13 Eating Disorders” and his exclusively edited book “Clinical Handbook of Eating
14 Disorders,” which were omitted from his Declaration and therefore concealed from the
15 Patent Board, were also highly relevant and important to his Declaration representations
16 regarding, as stated in his own words (in his Declaration), (i) “the successful use of
17 psychostimulants in the treatment of BN [Bulimia Nervosa]....” (see Exhibit 3, page
18 83), (ii) “over two decades of prior publications reported on the successful use of
19 psychostimulants in the treatment of bulimic episodes in BN patients....” (see Exhibit 3,
20 page 84), (iii) “At least since the early 1980’s, studies have shown psychostimulants to
21 be successful in treating the binge eating symptom of BN” (see page 99, Exhibit 3).
22 This is because in those two 2004 works, there is no evidence whatsoever to support that
23 stimulants (as used to treat ADHD) were acceptable and reasonably successful drugs in
24 treating Bulimia Nervosa or the symptom of binge eating in Bulimia Nervosa (absent
25 their use to treat ADHD for which they are clinically indicated); rather, the Defendant’s
26 own published and edited work from 2004 supports the conclusion that stimulants (as
27 used to treat ADHD) would not have been regarded as acceptable and reasonably
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1 successful drugs in treating Bulimia Nervosa or the symptom of binge eating in Bulimia
2 Nervosa (absent their use to treat ADHD for which they are clinically indicated).

3 21. The Defendant's egregious misrepresentation and miscontextualization of
4 the medical literature is only underscored by the fact that he cited the 2006 APA
5 (American Psychiatric Association) treatment guidelines for Bulimia Nervosa in his
6 Declaration (see Exhibit 3, page 14, Exhibit No. 1031) but he omitted from his
7 Declaration testimony the most materially relevant and important clinical teaching in
8 those guidelines with respect to the use of stimulants in the treatment of Bulimia
9 Nervosa or binge eating in Bulimia Nervosa, namely, that (bold emphasis and
10 parenthetical comments added) "**several case reports** [not extensive data] indicate that
11 methylphenidate [a stimulant as used to treat ADHD] may be helpful for **bulimia**
12 **nervosa patients with concurrent ADHD**" (see Exhibit 13, page 54) and "Case reports
13 indicate that methylphenidate [a stimulant as used to treat ADHD] may be helpful for
14 bulimia nervosa patients **with concurrent attention-deficit/hyperactivity disorder**
15 **(ADHD)** [III], **but it should be used only for patients who have a very clear**
16 **diagnosis of ADHD** [I]" (see Exhibit 13, page 20).

17 22. In this regard, the Defendant's misrepresentation and miscontextualization
18 on the use of stimulants to treat Bulimia Nervosa based on "extensive data" seriously
19 misled the Patent Board into thinking that stimulants were both a well-accepted and
20 well-studied treatment modality, as well as a reasonably successful one, for Bulimia
21 Nervosa, and therefore would have been "obvious" to use by a POSA as of September
22 2007 to treat Bulimia Nervosa (not ADHD) in its own right. Thus, when Defendant
23 represents that "Because it was well-established at the time of the invention that the
24 binge eating symptom of BN and BED is the same, a POSA would have had a
25 reasonable expectation of effectively treating the binge eating of BED with a
26 psychostimulant" (Exhibit 3, page 99), he egregiously misrepresents how the medical
27 literature would have been understood by a POSA for its "obviousness" and "reasonable
28

1 expectation of success,” by his own standard of interpretation and teaching no less
2 which clearly located stimulants for Bulimia Nervosa as irrelevant, non-existent and/or
3 obscure based on his own extensive surveys of the medical literature in 2004, one he
4 exclusively authored and the other he exclusively edited. More than that, he
5 contemptuously disregards the DSM-defined clinical context in which binge eating is
6 clinically present (*i.e.*, BED vs. BN), as if it too is irrelevant, non-existent and/or
7 obscure, even as the patent’s claims specifically and unambiguously recite that the use
8 of lisdexamfetamine is for the treatment of **Binge Eating Disorder as defined in the**
9 **DSM-IV-TR** (not “binge eating” generically).

10 23. Defendant Brewerton’s 2004 publications, made to a community of
11 “Persons of Ordinary Skill in the Art” (one vis-à-vis Psychiatry Times and the other in a
12 “clinical handbook”), makes it evident that he, as well as those POSA’s interested in
13 treating the disorder known as “Binge Eating Disorder as defined in the DSM-IV-TR”
14 (as recited in the patent’s claims), would have regarded the clinical context of the non-
15 specific symptom of “binge eating” (including its co-morbidity with another disorder,
16 like ADHD) as highly relevant and important in determining an acceptable and
17 reasonably successful pharmacologic treatment, much as Surman does in his analysis
18 (per paragraph 10 above) or as the 2006 APA treatment guidelines for Bulimia Nervosa
19 do (as noted above in paragraph 21). Defendant Brewerton’s 2004 publications make
20 self-evident that a POSA would have relied on evidence to support the treatment of non-
21 specific symptoms in their **proper DSM-defined clinical context**, as clearly featured in
22 U.S. Patent No. 8,318,813’s thirteen claims that, by method, diagnostically differentiate
23 binge eating in Bulimia Nervosa from binge eating in BED, as well as from binge eating
24 in Anorexia Nervosa. Again, Defendant willfully omitted disclosure of these highly
25 relevant and important 2004 “self-written or self-edited” references to the Patent Board
26 because they would have completely belied his testimony alleging the obviousness of
27 the ‘813 Patent’s claims to treat Binge Eating Disorder as defined in the DSM-IV-TR
28

1 with the stimulant drug lisdexamfetamine dimesylate and thus would have exposed the
2 misleading and deceptive nature of his testimony. Its disclosure would also have
3 demonstrated the non-obviousness and validity of the patent's claims.

4 24. Based on the totality of the evidence above, Defendant Brewerton
5 misrepresented the final statement of his Declaration that states (see p. 100,
6 Exhibit 3, paragraph 191), "I hereby declare that all statements made herein are of my
7 own knowledge are true and that all statements made on information and belief are
8 believed to be true; and further that these statements were made with the knowledge that
9 willful false statement and the like so made are punishable by fine or imprisonment, or
10 both, under Section 1001 of Title of the United States Code." His statements could not
11 be true in view of his own consideration and analysis of the medical literature to his
12 peers through published work which he failed to disclose to the Patent Board, as well as
13 in view of acceptable standards for the treatment of eating disorders laid out by the
14 American Psychiatric Association one year before the invention's priority date (Exhibit
15 13).

16 25. Defendant knew and was aware of the falsity of these misrepresentations, or
17 at the very least, had a reckless disregard for their truth or falsity. Defendant intended
18 that the misrepresentations be material and be acted upon by third-parties, and the
19 United States Patent Office's Patent Trial & Appeal Board did rely on the presumed
20 accuracy of Defendant's misrepresentations in granting an *Inter Partes Review* trial, on
21 which it later declared invalid U.S. Patent No. 8,318,813, which claimed exclusive
22 rights to Plaintiff's valuable inventions that were last owned by a company in which
23 Plaintiff is a Manager and Member, Lucerne Biosciences, LLC, and last exclusively
24 licensed by Lucerne Biosciences, LLC to LCS Group, LLC, a company in which
25 Plaintiff is CEO and Member.

26 26. The United States Patent Office's Patent Trial & Appeal Board was
27 ignorant of the falsity of Defendant's misrepresentations because it possessed
28

1 insufficient expertise in the area of eating disorders, obesity and stimulant drugs to
2 reasonably question Defendant's expertise and discover that Defendant's
3 misrepresentations were false and intended to deceive. Because Defendant Brewerton
4 was presented as an expert on the matters at issue, the United States Patent Office had a
5 right to rely on Defendant's misrepresentations.

6 27. Defendant's misrepresentations have proximately caused substantial damage
7 to Plaintiff, in an amount much greater than \$75,000. Specifically, Plaintiff estimates
8 that he has suffered in excess of \$300 Million (\$300,000,000) in damages, based on the
9 fact that the U.S. patent he solely invented, which was last owned by a company in
10 which he served as Manager and Member (Lucerne Biosciences, LLC) that itself
11 exclusively licensed the patent to a company in which he was CEO and Member (LCS
12 Group, LLC), encompassed method claims (*i.e.*, lisdexamfetamine dimesylate for the
13 treatment of Binge Eating Disorder as defined in the DSM-IV-TR) for an indication
14 approved by the Food & Drug Administration based on Phase III Clinical Trials in
15 patients with Binge Eating Disorder as defined in the DSM-IV-TR (in January 2015)
16 whose estimated market value to the pharmaceutical company marketing the drug for
17 the indication, Shire US Inc., has been valued in the range of \$200-\$750 Million in
18 revenues annually. As weighted over the duration of time that the patent would have
19 otherwise been valid and infringed over its lifetime to 2028, this amounts to \$2 to \$8
20 Billion, or more, aggregately in revenues to Shire from 2015 to 2028. References
21 alluding to annual revenues expected to Shire, including from Shire's CEO Dr.
22 Flemming Ornskov and "Wall Street analysts," can be found in Exhibits 14,15, and 16
23 attached hereto.

24
25 **SECOND CLAIM FOR RELIEF—DEFAMATION**

26 28. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates
27 them herein by reference.
28

1 29. Defendant's misrepresentations alleged herein were false and defamatory
2 statements, published to third parties, and non-privileged.

3 30. Defendant is at fault because he knew and was aware of the falsity of
4 his misrepresentations, or at the very least, had a reckless disregard for their truth or
5 falsity. Further, he persisted in his efforts to continue supporting his misrepresentations
6 and miscontextualization to invalidate U.S. Patent No. 8,318,813, even when made
7 aware of his misrepresentations and miscontextualization through evidence-based
8 profiling efforts that included his own published work which he concealed from the
9 Patent Board, as characterized in the communications transcript comprising Exhibit 7.

10 31. Defendant defamed the Plaintiff, an inventor, by publicly characterizing
11 the invention he invented as being merely "obvious" and as having a "reasonable
12 expectation of success" at the time of its invention, thus making it uninventive, despite
13 the fact that Defendant Brewerton himself made statements that supported the contrary
14 but which he failed to disclose to the Patent Trial & Appeal Board. In this regard, in
15 addition to the allegations stated above regarding how Defendant Brewerton failed to
16 disclose to the Patent Board materially relevant and important testimony he himself
17 published, he also stated in a publication he authored prior to the invention, titled
18 "Binge Eating Disorder: Recognition, Diagnosis and Treatment," that (bold emphasis
19 added) "**There are no published reports on the use of psychostimulants in the**
20 **treatment of BED.** Even though acutely administered stimulants suppress binge eating,
21 the risks of addiction and the possible induction of affective and psychotic
22 symptomatology **make this agent class undesirable as a therapeutic tool**" (see pages
23 20, 38, 45, 165, and 173 of Exhibit 4 for further explanation). Thus, by the Defendant's
24 own published standard by which to treat Binge Eating Disorder, the invention invented
25 by the Plaintiff related to the use of a psychostimulant to treat Binge Eating Disorder
26 was not only inventive, unorthodox and counter-intuitive but even radical and against
27 established medical guidance from eating disorder experts. Yet the Defendant failed to
28

1 disclose this publication and statement to the Patent Trial & Appeal Board for
2 consideration of the invention's novel, unorthodox and first-of-its-kind claimed methods
3 of treating Binge Eating Disorder as defined in the DSM-IV-TR (*not* "binge eating")
4 with a psychostimulant drug approved only, at the time of the invention's priority date
5 of September 13, 2007, for pediatric Attention Deficit Hyperactivity Disorder. Exhibits
6 4, 5, 6 and 7 collectively demonstrate that, at the time of the invention's priority date,
7 there were still no documented case reports for the treatment of Binge Eating Disorder
8 as defined in the DSM-IV-TR with a psychostimulant, except perhaps in such instances
9 where BED was co-morbid with ADHD and the stimulant was used as a primary
10 treatment for ADHD, despite the fact that the criteria for Binge Eating Disorder as
11 defined in the DSM-IV TR were in research and clinical usage for 13 years prior (as
12 defined by the same criteria in the DSM-IV from 1994-2000; see page 1 of Exhibit 6).
13 In this respect, the Plaintiff's invention stands as one of the most inventive and radical
14 inventions for the treatment of eating disorders in view of the medical literature on
15 treating Binge Eating Disorder, particularly in view Defendant Brewerton's 2004
16 publication "Pharmacotherapy for Patients with Eating Disorder" and his 2004 edited
17 "Psychopharmacology of Anorexia Nervosa, Bulimia Nervosa and Bing Eating
18 Disorder" which nowhere identify a single stimulant (as used to treat ADHD, like
19 lisdexamfetamine dimesylate) as an acceptable, reasonably successful treatment
20 modality for any eating disorder in which "binge eating" may be a central feature (i.e.,
21 Bulimia Nervosa, Binge Eating Disorder, Anorexia Nervosa, binge eating/purging type).
22 However, as characterized above, Defendant failed to disclose these materially
23 important and relevant publications, too, to the Patent Board for consideration of the
24 invention's novel and inventive features, itself a form of misrepresentation by material
25 omission of relevant and important context for addressing the patent's claims that
26 specifically involved administering a therapeutically effective amount of stimulant drug
27 to treat Binge Eating Disorder as defined in the DSM-IV-TR.

28

1 32. The publication of Defendant's misrepresentations caused special harm to
2 Plaintiff, in an amount much greater than \$75,000, as explained herein.

3
4 **THIRD CLAIM FOR RELIEF—NEGLIGENCE**

5 33. Plaintiff re-alleges all prior paragraphs of this Complaint and incorporates
6 them herein by reference.

7 34. Defendant owed the court and this Plaintiff a duty of due care in forming
8 his opinions and submitting materials relevant to whether Defendant's invention, owned
9 by companies in which he served management and membership roles during Shire's
10 *Inter Partes Review* proceeding (LCS Group, LLC first; then Lucerne Biosciences,
11 LLC), was "obvious" and had a "reasonable expectation of success" at the time of its
12 invention.

13 35. Defendant breached this duty and was negligent, gross negligent, and/or
14 was reckless, willful, and wanton in making the representations alleged herein.

15 36. Such representations as indicated herein were false and were relied upon
16 by the patent board and others in determining the subject issue at the *Inter Partes*
17 *Review*.

18 37. Defendant is at fault, because he knew and was aware of the falsity of
19 his misrepresentations, or at the very least, had a reckless disregard for their truth or
20 falsity. Further, he persisted in his efforts to continue supporting his misrepresentations
21 and miscontextualization to invalidate U.S. Patent No. 8,318,813, even when made
22 aware of his misrepresentations and miscontextualization through evidence-based
23 profiling efforts that included his own published work which he concealed from the
24 Patent Board, as characterized in the communications transcript comprising Exhibit 7.

25 38. Defendant was not subject to cross examination at the *Inter Partes*
26 *Review*, and, therefore Plaintiff had no opportunity to directly confront Defendant with
27 the falsity of his representations.
28

1 39. Defendant's misrepresentations actually and proximately caused injuries
2 and damages to Plaintiff as set forth herein in the Complaint, for which Defendant is
3 responsible.

4
5
6 **PRAYER FOR RELIEF**

7 Therefore, Plaintiff prays for the following relief:

- 8 A. A determination that Defendant is liable to Plaintiff for fraud;
9 B. A determination that Defendant is liable to Plaintiff for defamation;
10 C. A determination that Defendant is liable to Plaintiff for negligence;
11 D. An accounting for damages, including but not limited to Plaintiff's losses,
12 exemplary and punitive damages, pre-judgment and post-judgment interest, costs and
13 attorney fees; and
14 E. Such other and further relief as this Court deems just and proper.

15
16
17 Respectfully submitted,

18
19 Dated: January 18, 2017

By:



20 **Louis C. Sanfilippo, M.D.**
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